DRAFT

In the Claims:

1. (currently amended) A prosthesis for implant in a human body ~~containing a rupture indicator~~ comprising:

~~(a) an~~ at least one elastomeric ~~external~~ envelope; ~~of medical grade elastomer containing a fluid material and a biologically compatible chemical indicator for indicating rupture of said prosthesis, and~~

~~(b) an internal envelope of medical grade elastomer disposed within said external envelope, said internal envelope containing an implant~~ a filling material contained in the elastomeric envelope; and

a rupture indicator biocompatible with the human body contained within the elastomeric envelope capable of leaking out of the envelope and causing a detectable body change.

2. (currently amended) The prosthesis ~~containing a rupture indicator~~ of ~~C~~claim 1, wherein ~~said biologically compatible chemical~~ the rupture indicator is ~~a~~ at least one dye.

3. (currently amended) The prosthesis ~~containing a rupture indicator~~ of ~~C~~claim 2, wherein ~~said biologically compatible chemical~~ the rupture indicator is methylene blue.

4. (currently amended) The prosthesis ~~containing a rupture indicator~~ of ~~C~~claim 2, wherein ~~said biologically compatible chemical indicator~~ the rupture indicator is ~~at least one~~ selected from the group consisting of aurintricarboxylic acid (ATA), halogenated ATA, sulfonated ATA, sulfonated-halogenated ATA, phosphorylated ATA, anazolene sodium, eosine I bluish, eosine yellowish, erythrosine, Evan's blue (EB), fast green FCF, fuchin(e) acid, iodophthalein sodium, rose bengal, sulfobromophthalein sodium, suramin sodium, trypan blue, trypan red, rosaniline chloride, crystal violet, methyl blue, methyl green, coomassie blue, basic fuchsin, malachite green, brilliant green, aniline blue, brilliant cresyl blue, safranin O, ethyl violet, pararosaniline acetate, methyl violet, direct

DRAFT

yellow, direct red, ponceau S, ponceau SS, nitrosulfonazo III, chicago sky blue 6B, calcion or RG-13577, FD&C red No. 3, FD&C red No. 40, FD&C blue No. 1, ~~and~~ FD&C yellow No. 5, and combinations of these.

5. (currently amended) The prosthesis ~~containing a rupture indicator~~ of ~~C~~claim 1, wherein ~~said biological compatible chemical~~ the rupture indicator is an odour generating agent which generates a smell as the detectable body change when leaking out from ~~said~~ the prosthesis.

6. (currently amended) The prosthesis containing a rupture indicator of ~~C~~claim 1, wherein ~~said biological compatible chemical~~ the rupture indicator is a sensation agent which causes a local sensation as the detectable body change when leaking out from ~~said~~ the prosthesis.

7. (currently amended) The prosthesis ~~containing a rupture indicator~~ of ~~C~~claim 1, wherein ~~said~~ the prosthesis is a breast prosthesis.

8. (currently amended) The prosthesis ~~containing a rupture indicator~~ of ~~C~~claim 1, wherein ~~said~~ the prosthesis is ~~at least one~~ implanted in a portion of the human body selected from the group consisting of brow, nose, cheek, chin, lips, pectoral, triceps, ~~and~~ biceps, genitals, buttocks, and calf ~~prostheses~~.

9. (currently amended) The prosthesis ~~containing a rupture indicator~~ of ~~C~~claim 1, ~~wherein said external lumen~~ further comprises a ~~filling means~~ valve disposed in the elastomeric envelope for ~~filling said fluid material~~ adding or removing rupture indicator to or from the prosthesis.

DRAFT

10. (currently amended) The ~~cosmetic and reconstructive~~ prosthesis ~~containing a rupture indicator~~ of ~~C~~claim 9, wherein ~~said filling means~~ the valve is a self-sealing ~~valve~~.

11. (currently amended) A method of detecting rupture of a ~~cosmetic and reconstructive~~ prosthesis in a human body, comprising:

~~(a) surgically~~ implanting a prosthesis ~~containing a biologically compatible chemical indicator~~ having at least one elastomeric envelope and a filling material contained therein ~~for indicating rupture of said prosthesis~~ in a location of ~~a patient~~ the body ~~in need of said prosthesis~~; ~~and~~

adding into the prosthesis a rupture indicator biocompatible with the human body, capable of leaking out of the envelope and causing a detectable body change; and

~~(b)~~detecting the body change caused by the rupture ~~a change of a body secretion or peripheral blood for indication of leaking out of said~~ indicator upon leaking out from ~~said~~ the prosthesis.

12. (currently amended) The method of ~~C~~claim 11, wherein the detectable body change is a change in a ~~said~~-body secretion ~~is at least one~~ selected from the group consisting of urine, saliva, perspiration ~~and~~ feces, and combinations of these.

13. (currently amended) The method of ~~C~~claim ~~12~~ 11, wherein ~~said change~~ the detectable body change is a presence of ~~said chemical~~ the indicator or a metabolized product thereof in ~~said~~ at least one body secretion or peripheral blood.

14. (currently amended) The method of ~~C~~claim 12, wherein ~~said~~ the change is an odour ~~from said indicator in said~~ emanating from the body secretion.

DRAFT

15. (currently amended) The method of ~~C~~claim 12, wherein ~~said~~ the change is a color change of at least one ~~of said~~ body secretion.

16. (currently amended) The method of claim 11, wherein the detectable body change is ~~detecting rupture of a cosmetic and reconstructive prosthesis comprising:~~

~~(a) surgically implanting a prosthesis containing a biologically compatible chemical indicator for indicating rupture of said prosthesis in a location of a patient body in need of said prosthesis; and~~

~~(b) detecting~~ a change locally to a portion of the body around ~~said~~ the prosthesis ~~for indication of leaking out of said indicator from said prosthesis~~.

17. (currently amended) The method of ~~C~~claim 16, wherein ~~said change~~ the detectable body change is a local skin color change.

18. (currently amended) The method of ~~C~~claim 16, wherein ~~said change~~ the detectable body change is a local sensation.

19. (cancelled)

20. (new) The prosthesis of claim 1, further comprising two elastomeric envelopes, a first elastomeric envelope containing the filling material and a second elastomeric envelope containing the rupture indicator, the second envelope external to the first envelope, and wherein the detectable body change alerts a user of rupture of the external envelope and impending rupture of the first internal envelope and the filling material contained therein.

21. (new) The method of claim 11, wherein the prosthesis further comprises two elastomeric envelopes, first elastomeric envelope containing the filling material and a

DRAFT

second elastomeric envelope containing the rupture indicator, the second envelope external to the first.

22. (new) The method of claim 21, wherein the detectable body change alerts a user of rupture of the external envelope and impending rupture of the first internal envelope and filling material contained therein.

23. (new) A method of detecting impending rupture of a prosthesis in a human body, comprising:

implanting in a location of the body a prosthesis having two elastomeric envelopes, a first elastomeric envelope containing the filling material and a second elastomeric envelope external to the first envelope;

adding within the external envelope a rupture indicator biocompatible with the human body, capable of leaking out and causing a detectable body change upon rupture of the second external envelope; and

detecting the body change caused by the rupture indicator upon leaking out from the external envelope prior to rupture of the first internal envelope.